DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

NDA 20-013/S-008

UNIMED Pharmaceuticals, Inc.
Attention: Judy Athey
Manager, Regulatory Affairs
Four Parkway North, Suite 200
Deerfield, IL 60015

Dear Ms. Athey:

Please refer to your supplemental new drug application dated July 16, 1996, received July 17, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Maxaquin® (lomefloxacin) Tablets, 400 mg.

We acknowledge receipt of your submissions dated December 8, 1999 and March 2, 2000. Your submission of March 2, 2000 constituted a complete response to our June 3, 1997 action letter.

This supplemental new drug application provides for the following revisions to the Maxaquin® package insert:

1. The **CLINICAL PHARMACOLOGY,** Microbiology subsection was revised in order to modify the list of microorganisms that showed *in vitro* activity.

2. As we requested in our letter to Searle dated May 29, 1998, the following two sentences were deleted from the **Convulsions** paragraph in the **WARNINGS** section:

   "No evidence of an effect of lomefloxacin on the electrical activity of the brain has been demonstrated. Lomefloxacin does not alter cerebral blood flow or cerebral glucose uptake in the CNS based on positron emission tomography"

3. The **REFERENCES** section was updated.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 2, 2000).
Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-013/S-008." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Robin Anderson, Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Acting Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research